Generalized Linear Models (log link, Gamma family) adjusting for gender, age, BMI, type of intervention, complications and comorbidites. Costs are expressed in Euro 2013. **RESULTS:** 280 patients (171 workers, 61%, and 109 no-workers including people out of work, students, housewives and retirees, 39%) have been submitted to bariatric surgery and followed up to 1 year after the intervention. The overall social cost, including costs of intervention and 1-year follow up, was €11,310 (± €3,778). Direct medical costs amounted to €8,737 (± 2,527), representing the 77% of the overall cost, while direct non medical costs and indirect costs accounted for 13% and 10% (€1.497 ± €1,928 and €1,076 ± €1,675). No working conditions had an incremental effect on direct non-medical costs of €676 (95% CI: €212-€1,140, p=0.004). Working conditions increased indirect costs by €1,384 (95% CI: €1,002-€1,766, p=0.000). **CONCLUSIONS:** Socio-economic determinant such as employment status of patient led to significant impacts on direct non medical costs and indirect costs of a patient submitted to bariatric surgery.

PSY37

THE INDIRECT COSTS OF INFLAMMATORY BOWEL DISEASE (CROHN'S DISEASE AND ULCERATIVE COLITIS) ASSOCIATED WITH ABSENTEEISM IN POLAND IN 2013

Kawalec P, Mocko P, Malinowski K

Jagiellonian University Medical Collage Institute of Public Health, Krakow, Poland

OBJECTIVES: The aim of this study was to assess the indirect costs caused by absenteeism associated with inflammatory bowel disease (IBD) - (Crohn's disease – CD; and ulcerative colitis - UC) from the perspective of the Social Insurance Institution (ZUS) in Poland **METHODS:** The estimates were based on data provided by ZUS referring to year 2013 and concerning absence from work due to the illness (sick leave), the amount of short-term disability, the sufferers of which claim rehabilitation benefit, and the amount of permanent (or long-term) disability, the sufferers of which claim disability pension. Costs were calculated with Human Capital Approach methodology taking into account Gross Domestic Product (GDP) per capita equaled €10 278. **RESULTS:** Total indirect costs of CD, UC in the year 2013 calculated using GDP per capita in Poland were €7 817 156 and €8 990 313, respectively. Total indirect costs of IBD in the year 2012 and 2013 in Poland were €14 220 181 and € 16 807 469, respectively (an increase of nearly 15% because of substantial growth short-term disabilities). The highest component of indirect costs of IBD was sick leave (51%). Long and short-term disability costs constitute 39% (limited period – 19% and unlimited period 20%) and 10% of total indirect costs of IBD, respectively. One sick leave of person with IBD generated the cost of lost productivity equal €779 calculated using GDP per capita. Indirect cost of short-term disability for one entitlement to the benefit of rehabilitation were €7 314. Cost of one long-term benefit were much higher than short-term benefit and equaled for limited period €36 714 and unlimited period €941. Total long-term disability costs amounted €676 651. **CONCLUSIONS:** IBD in Poland generated high indirect costs. The main component was sick leave; rehabilitation benefit and disability pension generated lower costs of lost productivity.

PSY38

IDIOPATHIC PULMONARY FIBROSIS: HOSPITAL DISEASE MANAGEMENT AND ASSOCIATED COSTS

Cottin V[1], Schmidt A[2], Catella L[2], Porte F[3], Fernandez-Montoya C[3], Le Lay K[3], Bénard S[2]

[1]*Centre Hospitalier Universitaire de Lyon, Groupement Hospitalier Est-Hôpital Louis Pradel, Bron, France,* [2]*st[è]ve consultants, Oullins, France,* [3]*Boehringer Ingelheim France, Paris, France*

OBJECTIVES: Idiopathic pulmonary fibrosis (IPF) is a chronic, fibro-proliferative and fatal lung disease. A study was conducted to describe the causes and main comorbidities of hospitalized patients and associated costs in France. **METHODS:** A retrospective, observational study was set up using the French hospital discharge database (PMSI). Patients with a first hospitalization for IPF (ICD-10 code: J841) in 2008 were identified and followed during a 5-year period. As J841 code includes other fibrotic pulmonary diseases, an algorithm for data extraction was defined, with exclusion of age<50 and presence of a differential diagnosis in the following year (connective disease or pneumoconiosis). Patient characteristics, first stay and occurrence of events of special interest were described as well as associated costs. **RESULTS:** In 2008, 6,476 patients newly hospitalized for IPF were identified, with a mean age of 75.4±10.3 years, and 56% were men. The mean total cost of hospitalizations per patient for the 5-year follow-up period was €15,532±15,973. Main cost drivers were the serious events related to the disease, specifically acute exacerbation (37% of patients, with a 10% in-hospital mortality rate and a cost of €4,091±4,429/event), cardiac events (48% of patients with a 14% in-hospital mortality rate and a cost of €5,731±5,463/event), acute respiratory infections (44% of patients with a 18% in-hospital mortality rate and a cost of €7,471±7,981/event) and arterial thrombosis (12% of patients with a 20% in-hospital mortality rate and a cost of €7,467±7,216/event). Finally, 11% of patients received palliative care with a mean cost for the last year of life of €14,807±11,979 per deceased patient. **CONCLUSIONS:** This study is the first providing extensive data on hospital management for patients with IPF in France, demonstrating high burden and hospital cost, especially for acute respiratory deteriorations. These results could be used in economic evaluations for IPF patients in France.

PSY39

DIRECT MEDICAL COSTS ASSOCIATED WITH ANKYLOSING SPONDYLITIS IN CHINESE PATIENTS: ESTIMATIONS FROM CHINA PUBLIC HEALTH INSURANCE CLAIM DATA

Chen Y[1], Gao SQ[2], Liu Q[2], Liu R[3], Du F[1], Chen W[4]

[1]*Normin Health Changsha Representative Office, Changsha, China,* [2]*Beijing Brainpower Pharma Consulting Co. Ltd, Beijing, China,* [3]*Xian-Janssen China, Beijing, China,* [4]*Normin Health, Toronto, ON, Canada*

OBJECTIVES: To estimate direct medical costs associated with ankylosing spondylitis (AS) in publically insured Chinese patients. **METHODS:** China Health Insurance Research Association (CHIRA) claim data containing patients randomly selected from publically insured urban residents and workers across China was used as the data source to identify patients with AS and their insurance claim records in 2013 for in-patient care and out-patient care. The identified patients were stratified by AS-related medications for the comparisons on drug costs and non-drug medical costs. Generalized linear model (GLM) was conducted to assess the impact of the classified medications on on-drug medical costs after full adjustment of patient baseline characteristics including demography, AS-related to complications, and comorbidities. **RESULTS:** Among the identified 1299 patients with diagnosed AS, the AS-related medications included nonsteroidal anti-inflammatory drugs (NSAIDs) (n=234), immunosuppressant (n=146), combination of NSAID and immunosuppressant (n=626), biologics (n=60), and Chinese medications (n=233). The total medical costs associated with AE-related treatments ranged from RMB 4,565 for Chinese medication to RMB 24,585 for biologics treatment (1 RMB = 0.16 US$). However, biologics treatment and the combination treatment of NSAID and immunosuppressant had similar non-drug medical costs (RMB 7,039 versus RMB 7,450, p=0.164). GLM regression analysis further confirmed highly comparable non-drug medical costs associated with biologics (coefficient: 0.0639, p =0.741) relative to the combination treatment of NSAID and immunosuppressant. **CONCLUSIONS:** Among publically insured Chinese patients with AS, biologics treatments were associated with highly comparable non-drug medical costs as the combination treatment of NSAID and immunosuppressant. This finding suggests that biologics may effectively control health resource utilization through their superior treatment effects.

PSY40

COSTS OF ABSENTEEISM IN PSORIATIC AND ENTEROPATHIC ARTHROPATHIES BASED ON REAL-LIFE DATA FROM POLAND'S SOCIAL INSURANCE INSTITUTION DATABASE IN 2013

Kawalec P, Malinowski K

Jagiellonian University Medical Collage Institute of Public Health, Krakow, Poland

OBJECTIVES: The aim of this study was to assess the indirect costs caused by absenteeism associated with psoriatic and enteropathic arthropathies from the perspective of the Social Insurance Institution (ZUS) in Poland. **METHODS:** The estimates were based on data from the year 2013 concerning sick leave and the amount of short-term disability, the sufferers of which claim rehabilitation benefit, and the amount of long-term disability (permanent or fixed time), the sufferers of which claim disability pension. Costs calculated taking into account Gross Domestic Product (GDP) per capita equaled €10 278, Gross Value Added (GVA) per worker equaled €24 680 and Gross Income (GI) per worker equaled €7 339 were presented in 2013 prices. **RESULTS:** Total indirect costs of psoriatic and enteropathic arthropathies in the year 2013 calculated using GDP per capita, GVA and GI per worker in Poland were €7 341 217, €17 628 441 and €5 242 346, respectively. The highest component of indirect costs was permanent long-term disability (43%). Fixed period long-term disability and short-term disability costs constitute 20% and 9% of total indirect costs, respectively. In 2013 Poland's Social Insurance Institution database reported 2 100 patients that had 4 922 sick leave episodes, 180 short-term disability episodes and 80 long-term disability episodes. Indirect costs per patient associated with sick leave were €1 030, €2 474 and €736 calculated using GDP, GVA and GI, respectively. Indirect costs per patient associated with short-term disability were €298, €715 and €212 respectively and associated with long-term disability were as high as €2 168, €5 206 and €1 548, respectively. **CONCLUSIONS:** Psoriatic and enteropathic arthropathies in Poland generated high indirect costs. The main component was permanent long-term disability; short-term disability generated lower costs of lost productivity. The highest cost per patient was generated by permanent long-term disability.

PSY41

DIRECT COST OF MYELODYSPLASTIC SYNDROMES ASSOCIATED WITH A DELETION 5Q CYTOGENETIC ABNORMALITY (DEL5Q MDS) IN PATIENTS WHO ARE RED BLOOD CELL TRANSFUSION DEPENDENT IN MEXICO

Reyes-Lopez A[1], Lemus-Villafuerte F[2], Hernandez-Rivera G[3], Pacheco-Alvarez I[3], Lemus-Carmona EA[4]

[1]*Mexico's Children Hospital Federico Gomez, MEXICO, Mexico,* [2]*RCEI Consulting, MEXICO, Mexico,* [3]*Celgene Mexico, Mexico, Mexico,* [4]*Celgene S. de R.L. de C.V., Mexico D.F., Mexico*

OBJECTIVES: To estimate the direct cost of Del5q MDS from the perspective of the public healthcare system in Mexico **METHODS:** We evaluated the amount of resources utilized by patients with Del5q MDS from an expert panel of eight hematologist through the Delphi technique. Consensus was reached after two expert panel rounds and patterns of use were analyzed statistically. Unit costs of resources were extracted from institutional catalogues and annual cost estimations were performed for different health states. All values were expressed in US dollars of 2015 **RESULTS:** From the consensus of panel experts we found that management of patients with Del5q MDS at Mexican public healthcare institutions consisted of best supportive care with red blood cell (RBC) transfusions and erythropoiesis-stimulating agents, and since these patients are RBC-transfusion dependent, they receive 33 units of RBC per year resulting in a cost of US$5,265.60. Iron overload is the main complication of transfusion dependency resulting in an annual cost of US$1,782.11 attributable to congestive heart failure. Other resources used to the treatment of the disease are drugs, labs, and visits that contribute to the total annual cost of US$30,647.78 per patient **CONCLUSIONS:** MDS patients with 5q deletion impose a high economic burden to the public healthcare system in Mexico, although the incidence is lower than other hematological malignancies

PSY42

PHARMACOECONOMIC CONSIDERATIONS ABOUT BREAKTHROUGH CANCER PAIN

Vellucci R[1], Mediati RD[1], Gasperoni S[2], Piergallini LM[3], Valentino MC[4], Bruno GM[4], Di Matteo S[4], Colombo GL[5]

[1]*Palliative Care and Pain Therapy Unit-Careggi University Hospital Florence, Firenze, Italy,* [2]*Medical Oncology, AOU Careggi, Florence, Firenze, Italy,* [3]*S.A.V.E. Studi Analisi e Valutazioni Economiche, Milan, Italy,* [4]*S.A.V.E. Studi - Health Economics & Outcomes Research, Milan, Italy,* [5]*University of Pavia, Milan, Italy*

OBJECTIVES: BTcP is associated with a number of problematic physical, psychological/emotional and social complications which themselves are not only a relevant source of additional morbidity in these patients, but are also responsible for significant economic implications, for the patient, their relatives, for the healthcare system and society. **METHODS:** We performed a systematic literature search of PubMed electronic database through December 2014 and February 2015. The key words included "breakthrough cancer pain" and "cost effectiveness" or "economics" or "pharmacoeconomic," and MeSH terms included "breakthrough pain" and "neoplasms", or "economics" or "cost-benefit analysis" . There were no language or study design restrictions. A total of 20 articles were identified. Among the 10 included studies, there were two quality improvement projects, two survey studies, three decision-analytic models, one literature review, two pharmacoeconomics studies and one health economic framework. **RESULTS:** BTcP is associated with increased medical costs: direct medical costs, indirect costs, intangible cost. Direct medical costs might include hospital charges, cost of analgesics and other medications, radiotherapy, surgery, and clinician time; direct non-medical costs might include the cost of gas to drive to the clinic, parking during a clinic visit, highway tolls, overnight lodging for family/caregivers, meals for caregivers. Intangible costs include the patient's pain, suffering, depression, anxiety, loss of sleep, and fatigue, as well as the family's and/or caregiver's distress. **CONCLUSIONS:** Additional studies are needed to evaluate quality-of-life improvements and the cost-effectiveness of more systematic analgesic treatments for BTcP. By delineating all the factors describing the impact of BTcP on patients, providers, and society, a comprehensive health economic model will improve clinical decision making, optimize outcomes, and enhance satisfaction with the processes of care across all stakeholder levels. In the case of HTA in breakthrough cancer pain, ethical evaluations appear to be the most important assessment focus among the considered ones.

PSY43

COST OF FAMILIAL MEDITERRANEAN FEVER (FMF) DISEASE IN TURKEY

Aksu K[1], Dokuyucu O[2], Ertenli AI[3], Gul A[4], Karaaslan Y[5], Kasapcopur O[4], Kiraz S[6], Onat AM[7], Ozdogan AH[4], Ozbalas T[2], Ozen S[6], Saylan M[2], Senturk A[8], Tatar M[6], Tuna E[6], Turanli M[9], Yalcinkaya F[10]

[1]*Ege University Medical School, Izmir, Turkey,* [2]*Novartis, Istanbul, Turkey,* [3]*Hacettepe University Medical School, Ankara, Turkey,* [4]*Istanbul University Medical School, Istanbul, Turkey,* [5]*Ankara Numune Research Hospital, Ankara, Turkey,* [6]*Hacettepe University, Ankara, Turkey,* [7]*Gaziantep University Medical School, Gaziantep, Turkey,* [8]*Polar Health Economics and Policy Consultancy, Ankara, Turkey,* [9]*Novartis Pharma, Istanbul, Turkey,* [10]*Ankara University Medical School, Ankara, Turkey*

OBJECTIVES: Familial Mediterranean Fever disease (FMF) is an autosomal recessively inherited disease characterized by recurrent, self-limited febrile attacks with serositis, synovitis, and occasionally skin involvement. AA amyloidosis is the most serious complication of FMF and can be life-threatening. Daily colchicine is considered standard of care, and is expected to prevent attacks and amyloidosis in most patients. The objective of this study is to estimate the cost burden of FMF in Turkey from payer perspective. **METHODS:** Delphi technique was applied to determine the type and the amount of resources used in FMF based on physicians views. The Delphi method solicits the opinion of an expert panel through a carefully designed questionnaire which in this case included questions on: type, frequency and duration of the health care resources used for diagnosis and treatment of the disease, epidemiology of the disease and colchicine resistant patients. Ten key opinion experts were involved in the study.The responses were analysed and discussed in a face to face meeting followed by consensus building steps. Unit costs of resources used were obtained from payer' Reimbursement Guideline-List of Procedure Fees Per Service. **RESULTS:** The prevalence of the disease is estimated 0.1%. 65% of patients are responders to colchicine treatment, 30% are partial responders and 2-5% are colchicine resistant. The cost of diagnosis was 549,59TL, cost of standard treatment was 3.233,86TL, cost of treatment for colchicine resistant patients was 69.254,32TL per patient. The cost of treatment of two major complications, amyloidosis and renal failure were estimated as 8.628,98TL and 16.120TL respectively. The annual total cost of the disease to the SSI was found as 547.945.305TL without complications and 750.921.801TL with complications. **CONCLUSIONS:** FMF is highly prevalent in Turkey and there are unmet needs for colchicine resistant patients. The burden of disease is increasing with long term complications and colchicine resistance.

PSY44

SOCIETAL AND NON-HEALTHCARE COSTS ASSOCIATED WITH ATYPICAL HAEMOLYTIC URAEMIC SYNDROME IN THE UK: RESULTS OF A PATIENT SURVEY

Palkmets O, Balvanyos J, Parthenaki I, Alnwick-Allu K, Hutchings A

Dolon Ltd, London, UK

BACKGROUND: Atypical haemolytic uraemic syndrome (aHUS) is a progressive, life-threatening, and ultra-rare disease with an estimated prevalence of 5.5 persons per million in England (AGNSS in 2012). **OBJECTIVES:** There is a lack of literature describing the economic and humanistic burden of aHUS. A patient survey was undertaken to evaluate the impact of aHUS on patients, their carers and society in the UK. **METHODS:** aHUS patients and their carers were recruited by the UK aHUS Patients and Families Support Group and were asked to complete an online questionnaire. Respondents described the impact of aHUS on daily activities, work and out-of-pocket expenses. **RESULTS:** 37 patients with aHUS completed the survey. 23 patients were above 18 years of age (23/35). 61% of adult patients (14/23) were employed, 39% (9/23) were not currently in employment; of these, 33% (3/9) were retired. The rate of economically inactive adults among aHUS patients exceeded the UK national average by 20%. Based on the UK median earning (ONS 2012), an annual lost productivity cost of £2,650 per aHUS patient or £472 of lost tax revenues was calculated. 54% (20/37) of aHUS patients had a carer, of which 82% (16/20) were informal carers (ie. family members). On average, carers lost 18 hours of paid work per week and estimated £12,190 lost productivity/£2,170 lost tax revenues per carer. The following out-of-pocket expenses (per patient per year) were estimated using the survey results and findings from the literature: cost of travel to receive healthcare (£780), household expenses (£136), cost of moving home (£65) and lost accommodation costs (£214). **CONCLUSIONS:** Patient survey results showed that aHUS has a substantial economic burden to patients, their carers and society. The total economic burden from lost productivity of patients, carers and out-of-pocket expenses was estimated to be £9,243 per aHUS patient per year.

PSY45

THE BUDGET IMPACT OF ORPHAN DRUGS IN THE US AND CANADA: A 2007-2013 MIDAS SALES DATA ANALYSIS

Divino V[1], DeKoven M[1], Kim T[2], Kleinrock M[1], Wade RL[1], Kaura S[3]

[1]*IMS Health, Fairfax, VA, USA,* [2]*Celgene Corporation, Mississauga, ON, Canada,* [3]*Celgene Corporation, Summit, NJ, USA*

OBJECTIVES: In the United States (US), the 1983 Orphan Drug Act (ODA) established incentives for the development of drugs that treat rare or orphan diseases (defined as diseases affecting < 200,000 Americans). Health Canada is currently developing an orphan drug framework (for diseases affecting ~5 in 10,000 Canadians). This study measured total annual expenditures of orphan drugs in the US and Canada (2007-13) and estimated future (2014-18) orphan drug expenditures. **METHODS:** Branded, orphan drugs approved by the US Food and Drug Administration (FDA) between 1983-2013 were identified (N=356). The Canadian analysis only included US orphan drugs with the same orphan indication(s) approved in Canada. Adjustment via disease factoring was applied to products with multiple indications (both orphan and non-orphan) using available data sources to isolate orphan-indication sales only. The IMS MIDAS database was used to assess total orphan drug expenditures, calculated annually from 2007-2013 and evaluated as a proportion of total annual pharmaceutical drug expenditures (all reported in 2014 US dollars). **RESULTS:** Between 2007-2013, expenditures were measured for a final N=316 and N=147 orphan drugs in the US and Canada, respectively. In the US, total orphan drug expenditures accounted for $15.0-$30.0 billion in 2007-13, representing 4.8-8.9% of total U.S. pharmaceutical expenditures, respectively. In Canada, orphan drug expenditures totaled $557.7-$1,005.8 million in 2007-13, representing 3.3-5.6% of total Canadian pharmaceutical expenditures, respectively. Future trend analysis (2014-18) suggests a slowing down in growth of orphan drug expenditures. **CONCLUSIONS:** While the number of available orphan drugs and associated expenditures increased over time, these drugs benefit many people with previously underserved rare conditions. From a societal perspective, the overall budget impact of orphan drugs is small and has remained fairly stable relative to total pharmaceutical expenditures. Concerns that growth in orphan drug expenditures may lead to unsustainable drug expenditures do not appear to be justified.

PSY46

COMPARING THE COST-EFFECTIVENESS OF APCC VS RFVIIA IN ON-DEMAND TREATMENT OF BLEEDS IN HEMOPHILIA A PATIENTS WITH INHIBITORS: A BRAZILIAN PUBLIC HEALTH SYSTEM PERSPECTIVE

Carmo EV[1], Oladapo AO[2], Rothschild C[1]

[1]*Baxter Hospitalar Ltda, São Paulo, Brazil,* [2]*BaxAlta Inc., Cambridge, MA, USA*

OBJECTIVES: The development of inhibitors is the most challenging complication of hemophilia treatment. Bypassing agents (i.e. aPCC and rFVIIa) remain the therapy of choice but account for a significant proportion of treatment cost. This study aims to compare the cost-effectiveness of aPCC vs. rFVIIa in on-demand treatment from the Brazilian public health system perspective. **METHODS:** A literature based cost model was developed based on utilization and efficacy (evaluated at 2, 6, 12, 24, 36 and 48 hours after infusion) data from the FENOC (head-to-head) trial which investigated the equivalency of the clinical efficacy of aPCC and rFVIIa in on-demand treatment. The median (range) treatment dose was 84.6 (51.5-100) U/kg and 212.5 (98.6-261.8) µg/kg for aPCC and rFVIIa, respectively. Hemostatic efficacy ranged from 75% to 97.6% for aPCC and 60.4% to 85.4% for rFVIIa. Bleed resolution rate also ranged from 53.2% to 95.1% for aPCC and 38.3% to 92.7% for rFVIIa. Cost analysis was limited to drug costs and prices were obtained from the 2014 Brazilian Official Diary: U$0.71/U and U$0.64/µg for aPCC and rFVIIa, respectively. One-way sensitivity analyses were performed to determine model robustness when dose and price were varied by ±25%. **RESULTS:** The cost/kg per on-demand bleed treatment was 55.9% lower for aPCC compared to rFVIIa. The cost/kg per treatment efficacy was 64% to 79% lower for aPCC compared to rFVIIa. Similarly, cost/kg per resolved bleed was 68% to 81% lower for aPCC compared to rFVIIa. Results remained robust for all one-way sensitivity analyses conducted. Given, an estimated total inhibitor population of 684 in Brazil, total saving with aPCC can vary from U$13.2-U$53.2 million depending on market share. **CONCLUSIONS:** aPCC was the dominant therapy in on-demand treatment. Using the current Brazilian prices, for each bleed treated with rFVIIa about 2.3 bleeds could be treated with aPCC at comparable cost.

PSY47

ANALYSIS OF DIRECT COSTS ASSOCIATED WITH CYSTIC FIBROSIS IN SINGLE CENTER IN SLOVAKIA: 5 YEARS REVIEW

Babela R, Ferancova D

St. Elizabeth University of Health and Social Work, BRATISLAVA, Slovak Republic

OBJECTIVES: Treatment of Cystic Fibrosis (CF) as rare disease is generally perceived as highly expensive, but we did not have more specific national or local costs data. Since patients are on lifelong treatment we tried to analyzed direct costs associated with CF in single center. **METHODS:** We analyze direct costs associated with treatment management of patients with CF in selected center in Slovakia from 2009 till 2013. We reviewed 182 adult patients regularly visiting CF centrum. We distributed patients according to age that is closely connected with CF prognosis. We included: treatment costs, healthcare procedures, medical devices and hospitalization costs. We used perspective of healthcare provider. We chose cost-of-illness, prevalence-based approach and compared costs based on time/year, gender, age and type of procedure. **RESULTS:** We have found that adult patients with CF between age 30 and 35 (21 patients) consumed most resources from 2009 till 2012, but most significantly